

88052-8

12/13/2012

1/14



U S ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
 Registration Division (7505C)
 1200 Pennsylvania Ave N W
 Washington D C 20460

EPA Reg Number

88052-8

Date of Issuance

DEC 13 2012

NOTICE OF PESTICIDE

☒ Registration
☐ Reregistration
 (under FIFRA as amended)

Term of Issuance

Conditional

C712 0 FOR DOGS

Name and Address of Registrant (include ZIP Code)

Horizon Valley Generics, Inc
c/o Pyxis Regulatory Consulting, Inc
4110 136th Street NW
Gig Harbor, WA 98332

Note Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant the above named pesticide is hereby registered//reregistered under the Federal Insecticide Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment the Administrator on his motion may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you

- 1 Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under section 4 of FIFRA
- 2 Submit within 12 months of the date of issuance of this Registration Notice, acceptable guideline studies for Storage Stability study (OPPTS GLN 830 6317) and Corrosion Characteristics study (OPTS GLN 830 6320) for this product
- 3 Change the product registration number to "EPA Reg No 88052-8"
 (continued on page 2)

Signature of Approving Official

See page 2

Richard Gebken Product Manager (10)
 Insecticide Branch Registration Division (7505P)

Date

DEC 13 2012

EPA Form 8570 6

Conditions of acceptance

2/14

- 1 This registration is now time-limited and expires two years from the date of this letter
- 2 Please consider limiting the formulations of this product to one basic confidential statement of formula The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future
- 3 You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2012

Please flag any Confidential Business Information as such Enhanced incident reporting should be submitted to the Product Manager Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn Karlton Keller)

The following is a list of information that must be included in the quarterly reports for each incident

EPA Registration Number

Product name (brand name)

Lot #

Where purchased internet, store, veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred (mm/dd/yyyy)

State in which the incident occurred (standard 2 letter abbreviation)

Registrant case #

Species dog, cat, other (specify)

Breed (as reported by pet owner)

Age months or years

Sex M, F, or neutered

Weight pounds

Primary Route of Exposure dermal, oral, other animal, inhalation, other

Body System neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset (hours, days)

Treated by veterinarian yes or no

First time product used yes or no

Misuse use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code death, major, moderate, minor

Outcome died, recovered, still treated, unknown

- 4 Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details

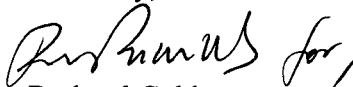
3/17

- All incidents should be reported including all minor dermal and ocular irritation reports
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.

Report aggregate incidents, but do not combine moderate and minor incidents

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action. If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at Benmhend.driss@epa.gov

Sincerely,



Richard Gebken
Product Manager 10,
Insecticide Branch
Registration Division (7505P)

Enclosure Label Stamped "with Comments"

9/14

- [Label Directions and Container (Carton) and Package Insert for
0 023 fl oz (0 67 mL) (applicators) (pipettes)]
- [Label Directions and Container (Carton) and Package Insert for
0 045 fl oz (1 34 mL) (applicators) (pipettes)]
- [Label Directions for Container (Carton) and Package Insert for
0 091 fl oz (2 68 mL) (applicators) (pipettes)]
- [Label Directions and Container (Carton) and Package Insert for
0 136 fl oz (4 02 mL) (applicators) (pipettes)]

[Optional text appears in brackets – the final label may include some or all optional text on front, back, side, or inside label panels]

ACCEPTED
With COMMENTS
In EPA Letter Dated

DEC 13 2012

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg No

88052-8

- [CARTON – 3 x 0 023 FL OZ PACKAGE]
- [CARTON – 3 x 0 045 FL OZ PACKAGE]
- [CARTON – 3 x 0 091 FL OZ PACKAGE]
- [CARTON – 3 x 0 136 FL OZ PACKAGE]

C712 0 FOR DOGS

[Alternate Brand Names]

- [SpringLine (for dogs & puppies – up to 22 lbs and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 23-44 lbs and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 45-88 lbs and 8 weeks or older) – picture of dog in weight class]
- [SpringLine (for dogs & puppies – 89-132 lbs and 8 weeks or older) – picture of dog in weight class]

[FOR DOGS & PUPPIES – Use only on dogs weighing up to 22 lbs and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 23-44 lbs and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 45-88 lbs and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 89-132 lbs and 8 weeks or older]

Optional Marketing Claims [Fleas Ticks Chewing Lice]

- [Fast-acting long-lasting convenient spot treatment for control of fleas ticks and chewing lice]
- [Waterproof]
- [C712 0 FOR DOGS provides convenient and effective flea tick and chewing lice control for dogs and puppies]
- [Fast acting and long-lasting]
- [Prevents re-infestation]
- [Convenient to use]
- [Kills (newly emerged) adult fleas before they lay eggs]
- [Controls fleas which may cause flea allergy dermatitis]
- [Kills all stages of brown dog ticks (*R. sanguineus*) American dog ticks (*D. variabilis*) lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)(which may carry Lyme disease)]
- [Rapidly eliminates infestations with chewing lice]
- [Aids in control of sarcoptic mange infestations]
- [Can be used on breeding pregnant and lactating bitches]

- [Waterproof (water resistant)]
- [Prevents infestation]
- [Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite dermatitis)]
- [Protects for one month]
- [Effective monthly treatment of fleas ticks and lice]
- [Remains effective after bathing and swimming]
- [Kills ticks that may transmit Lyme disease Rocky Mountain spotted fever babesiosis ehrlichiosis bartonellosis hepatozoonosis]
- [(Easy) (fast)(effective) control of fleas ticks and lice]
- [Kills fleas (ticks) (lice)]
- [Kills fleas that may cause anemia]
- [Optional graphics Picture of Flea]
- [Optional graphics Picture of tick]
- [Optional graphics Picture of louse]
- [Contains the proven effective topical fipronil]
- [Contains the proven effective topical fipronil found in Frontline*]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Eliminates infestations with chewing lice]
- [Controls and prevents re-infestation]
- [Kills all stages of deer ticks]
- [Prevents infestations of adult fleas and adult ticks]
- [Apply monthly]
- [Controls mites that may cause sarcoptic mange]
- [Best results when used monthly (year round)]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- 3 Doses
- Controls flea re-infestation for up to one month (4 weeks)
- [Contains (Fipronil) the active ingredient used in Frontline Top Spot® for Dogs]
- [C712 0 FOR DOGS is not manufactured by or distributed by Merial Limited]
- [Frontline Top Spot® is a registered trademark of Merial Limited]
- [Contains Fipronil (the active ingredient used in Frontline Top Spot® for Dogs)]
- [Compare to Frontline Top Spot® for Dogs]
- [C712 0 FOR DOGS is not manufactured by or distributed by Merial Frontline is a registered trademark of Merial]

EPA Reg No 88052-I

EPA Est 74720-DEU-01

ACTIVE INGREDIENT

Fipronil

9.7%

OTHER INGREDIENTS

90.3%

TOTAL

100.0%

KEEP OUT OF REACH OF CHILDREN

6/14

CAUTION

See [back (side) panel and insert] for additional Precautionary and First Aid Statements

NET CONTENTS

[Three (3) 0.023 fl oz (0.67 mL) (applicators) (pipettes)]

[Three (3) 0.045 fl oz (1.34 mL) (applicators) (pipettes)]

[Three (3) 0.091 fl oz (2.68 mL) (applicators) (pipettes)]

[Three (3) 0.136 fl oz (4.02 mL) (applicators) (pipettes)]

[CAT PROHIBITION ICON]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Side Effects: Monitor your dog after application. Side effects may include skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

C712 0 FOR DOGS 8 weeks or older

C712 0 FOR DOGS contains the active ingredient fipronil that effectively targets fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. Do not use on rabbits or on other animals.

[Precaución al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows:

To remove and open (applicator) (pipette) See label insert for opening instructions

INSTRUCTIONS FOR APPLYING PRODUCT

To apply C712 0 for Dogs Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades Squeeze (applicator) (pipette) applying entire contents in a single spot to the dog's skin Avoid superficial application to the dog's hair Allow area to dry before touching treated area Only one (applicator) (pipette) per treatment is needed

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine)

C712 0 for Dogs can also be used for the treatment and control of flea tick and chewing lice infestations on breeding pregnant and lactating bitches C712 0 for Dogs aids in the control of sarcoptic mange infestations Multiple monthly treatments are recommended for the elimination of mites

FREQUENCY OF APPLICATION

When used monthly C712 0 for Dogs completely controls flea tick and chewing lice infestations Research demonstrates that C712 0 for Dogs kills adult fleas up to three months Although C712 0 for Dogs can control fleas for up to three months if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis a once monthly application may be needed C712 0 for Dogs kills ticks for at least one month A once monthly application is recommended where tick control is needed A once monthly application is recommended where chewing lice are present C712 0 for Dogs remains effective even after bathing water immersion or exposure to sunlight Do not reapply C712 0 for Dogs for 30 days

Manufactured for

Horizon Valley Generics Inc
1201 Walnut Street Suite 2900
Kansas City Missouri 64106

MADE IN Germany

C712 0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics Inc
©2012 Horizon Valley Generics Inc All rights reserved

8/14

[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0 023 FL OZ PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0 045 FL OZ PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0 091 FL OZ PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0 136 FL OZ PACKAGE]

C712 0 FOR DOGS 8 weeks or older

EPA Reg No 88052-I

[EPA Est 74720-DEU-01]

ACTIVE INGREDIENT

Fipronil

9.7%

OTHER INGREDIENTS

90.3%

TOTAL

100.0%

Kills fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice

KEEP OUT OF REACH OF CHILDREN

CAUTION

C712 0 for Dogs contains the active ingredient fipronil that effectively targets fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. Do not use on rabbits or on other animals.

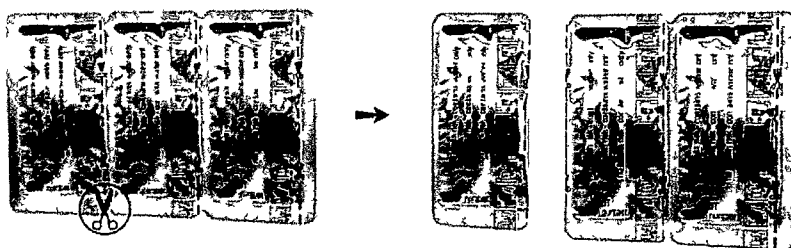
Precaución al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you.)

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows:

To remove and open (applicator) (pipette)

[ILLUSTRATIONS FOR OPENING PRODUCT]

- 1 Cut along scissor cut line to separate unit



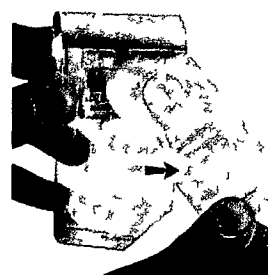
- 2 Turn unit over and cut corner at bulb end



- 3 From cut corner peel backing completely off from bottom to top



- 4 Remove the applicator



[ILLUSTRATIONS FOR APPLYING PRODUCT]

To apply C712 0 for Dogs Place (applicator) (pipette) tip through dog s hair to the skin level between the shoulder blades Squeeze (applicator) (pipette) applying entire contents in a single spot to the dog s skin Avoid superficial application to the dog s hair Allow area to dry before touching treated area Only one (applicator) (pipette) per treatment is needed

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail

OR [Alternate application method]

For dogs & puppies weighting up to 22 lbs Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine)

C712 0 for Dogs can also be used for the treatment and control of flea tick and chewing lice infestations on breeding pregnant and lactating bitches C712 0 for Dogs aids in the control of sarcoptic mange infestations Multiple monthly treatments are recommended for the elimination of mites

FREQUENCY OF APPLICATION

When used monthly C712 0 FOR DOGS completely controls flea tick and chewing lice infestations Research demonstrates that C712 0 FOR DOGS kills adult fleas up to three

10/14

months Although C712 0 FOR DOGS can control fleas for up to three months if there is a high risk of re-infestation or if the pet has fleas which may cause flea allergy dermatitis a once monthly application may be needed C712 0 FOR DOGS kills ticks for at least one month A once monthly application is recommended where tick control is needed A once monthly application is recommended where chewing lice are present C712 0 FOR DOGS remains effective even after bathing water immersion or exposure to sunlight Avoid contact with treated area until dry Do not reapply C712 0 FOR DOGS for 30 days

[CAT PROHIBITION ICON]

DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours If applied to a cat or ingested by a cat contact your veterinarian

Side Effects Monitor your dog after application Side effects may include skin irritation such as redness scratching or other signs of discomfort Gastrointestinal signs such as vomiting or diarrhea have also been reported If these or other side effects occur consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435

- 11/14

[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0 023 FL OZ PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0 045 FL OZ PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0 091 FL OZ PACKAGE]
[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0 136 FL OZ PACKAGE]

C712 0 FOR DOGS

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment

IF ON SKIN OR CLOTHING Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOTLINE NUMBER Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact the ASPCA Animal Poison Control Center at 1-888-426-4435 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION Causes moderate eye irritation. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities while rare, may occur after using any pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call the ASPCA Animal Poison Control Center at 1-888-426-4435 for assistance.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call the ASPCA Animal Poison Control Center at 1-888-426-4435.

[GRAPHICS/PICTURES]

[PRODUCT BAR CODE]

12/14

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage and disposal

Pesticide Storage Store unused product in original container only out of reach of children and animals

PESTICIDE DISPOSAL If partly filled call your local solid waste agency or 1-800-CLEANUP for disposal instructions Never place unused product down any indoor or outdoor drain

CONTAINER DISPOSAL If empty Non refillable container Do not reuse this container If empty Place in trash or offer for recycling if available

HOW SUPPLIED

C712 0 FOR DOGS is available in convenient sizes for small dogs and puppies 8 weeks or older and up to 22 lbs medium dogs 23-44 lbs large dogs 45-88 lbs and extra-large dogs 89-132 lbs

up to 22 lbs	Contains 3 - 0 023 fl oz (0 67 mL) (applicators) (pipettes)
23-44 lbs	Contains 3 - 0 045 fl oz (1 34 mL) (applicators) (pipettes)
45-88 lbs	Contains 3 - 0 091 fl oz (2 68 mL) (applicators) (pipettes)
89-132 lbs	Contains 3 - 0 136 fl oz (4 02 mL) (applicators) (pipettes)

WARRANTY

To the extent consistent with applicable law Horizon Valley Generics Inc and/or seller makes no warranty expressed or implied concerning the use of this product other than indicated on the label Buyer assumes all risk of use resulting from the handling of this product Seller shall return the purchase price or at the election of the seller replace the product

Manufactured for

Horizon Valley Generics Inc
1201 Walnut Street Suite 2900
Kansas City Missouri 64106

[MADE IN Germany]

C712 0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics Inc

©2012 Horizon Valley Generics Inc All rights reserved

[Text for Back of Blister Pack]

Pictogram with scissors and cut-line (see photo above)

Keep Out of Reach of Children

Read directions before use

CAUTION

Cat prohibition icon



DO NOT USE ON CATS

Use **ONLY** on Puppies up to 22 lbs and 8 weeks or older

0 023 fl oz

Use **ONLY** on Dogs 23-44 lbs and 8 weeks or older

0 045 fl oz

Use **ONLY** on Dogs 45-88 lbs and 8 weeks or older

0 091 fl oz

Use **ONLY** on Dogs 89-132 lbs and 8 weeks or older

0 136 fl oz

C712 0 for Dogs

Fipronil 9.7%

EPA Reg No 88052-I

Lot No

[Text for Back of Pipette]

Keep Out of Reach of Children

Read directions before use

CAUTION

DO NOT USE ON CATS

C712 0 for Dogs

Fipronil 9.7%

EPA Reg No 88052-I

Lot No

(Use **ONLY** on Puppies up to 22 lbs and 8 weeks or older

0 023 fl oz)

(Use **ONLY** on Dogs 23-44 lbs and 8 weeks or older

0 045 fl oz)

(Use **ONLY** on Dogs 45-88 lbs and 8 weeks or older

14/14

0 091 fl oz)

(Use ONLY on Dogs 89-132 lbs and 8 weeks or older

0 136 fl oz)